Claims

What is claimed is:

1. A non-human animal that (1) has an irritated GI tract; and (2) has been manipulated by the hand of man to be allergic to an orally-delivered antigen.

2. A non-human animal that has an allergic response to an orally-delivered antigen, wherein the allergic response is mediated by antigen-specific IgE antibodies.

3. A non-human animal that has an allergic response to an orally-delivered antigen and has antigen-specific IgE levels of at least about 500 ng/ml.

4. The non-human animal of claim 3 wherein the antigen-specific IgE levels are at least 1000 ng/ml.

5. The non-human animal of claim 3 wherein the antigen-specific IgE levels are at least 1500 ng/ml.

6. A non-human animal characterized in that, when presented with a potential sensitizing antigen in combination with cholera toxin, the animal either develops an immune reaction characterized by anaphylaxis to oral challenged with the antigen or does not develop such a response, the development or non-development of a response being predictors of the likelihood that human subjects will anaphylax to oral exposure to the antigen.

7. A kit comprising:
the non-human animal of claim 2 or claim 6; and
reagents to detect antigen-specific IgE.

8. A kit comprising:

a non-human animal characterized or that

1) the animal has an irritated GI tract; and

2) when exposed to peanut in carbirati with choleatoxin administered, the animal becomes sensitized and will araphylax to orally-adminstered peanut; and sensitizing reagents including choleatoxin.

9. The kit of claim 6 wherein the aminal demonstrates an ability to be sensitized to orally-delivered anigens to which humans become sensitized, but not to orally-delivered antigens to which humans do not become sensitized.

10. The kit of claim 9 wherein the orally-delivered antigens to which humans do not become sensitized include those to which less than 10% of the human population.

11. The kit of claim 9 wherein the orally-delivered antigens to which humans do not become sensitized include those to which less than 1% of the human population.

11a. The kit of claim 9 wherein the orally-delivered antigens to which humans do not become sensitized include corn.

12. The animal of claim 1 wherein the animal anaphylaxes when contacted with the sensitizing antigen.

13. The animal of claim 1 wherein the animal is a non-human mammal.

14. The animal of claim 1 wherein the animal is a rodent.

15. The animal of claim 1 wherein the animal is selected from the group consisting of rat, mouse, rabbit, ferret, hamster, and guinea pig.

16. The animal of claim 1 wherein the animal is a rat.

17. The animal of claim 1 wherein the animal is a mouse.

18. The animal of claim 1 wherein the animal is a C3H/HeJ mouse.

19. The animal of claim 1 wherein the animal is a non-human primate.

20. The animal of claim 1 wherein the animal is selected from the group consisting of baboons, monkeys, gorillas, apes, and orangutans.

21. The animal of claim 1 wherein the antigen to which the animal is allergic is one to which at least one human is allergic and that poses an anaphylactic risk to at least one allergic human.

22. The animal of claim 1 wherein the antigen is an anaphylactic antigen.

23. The animal of claim 1 wherein the antigen is a food antigen.

24. The animal of claim 23 wherein the food antigen is selected from the groups consisting of fruit antigens, berry antigens, nut antigens, bean antigens, milk antigens, dairy product antigens, peanut antigens, seed antigens, fish antigens, and shellfish antigens.

25. The animal of claim 23 wherein the food antigen is a peanut antigen.

26. The animal of claim 23 wherein the food antigen is a milk antigen.

27. The animal of claim 1 wherein the antigen is an environmental antigen.

28. The animal of claim 27 wherein the environmental antigen is selected from the groups consisting of weed pollen antigens, grass pollen antigens, tree pollen antigens, mite antigens, animal antigens, animal dander antigens, fungal antigens, and insect antigens.

29. The animal of claim 27 wherein the environmental antigen is a latex antigen.

30. The animal of claim 1 wherein the antigen is a pharmaceutical agent.

31. The animal of claim 1 wherein the the animal does not have an allergic response to non-allergenic food antigens.

32. The animal of claim 31 wherein the non-allergenic antigens are derived from corn.

33. A method of using a sensitized an animal to detect the presence of antigen, the method comprising the steps of:

providing an animal that is sensitized to an antigen and that is not able to be sensitized to antigens that humans are not normally allergic;

providing a test product;

contacting animal with test product; and

determining immune response of animal.

34. The method of claim 33 wherein the antigen that humans are not normally allergic comprises antigens derived from corn.

35. The method of claim 33 wherein the test product is a food product.

36. The method of claim 33 wherein the test product is a skin product.

37. The method of claim 33 wherein the test product is a pharmaceutical composition.

37a. The method of claim 33 wherein the step of contacting comprises adminstering the test product orally.

38. A method of assessing antigenicity of a test substance, the method comprising steps of:

providing a non-human animal as a model system;

exposing the non-human animal to a test substance to which one or more humans are expected to become exposed via a particular route, the exposure to the non-human animal being via the same route; and

determining whether the non-human animal can be made to be allergic to the test substance.

39. The method of claim 38, wherein the step of providing comprises providing a non-human animal that is susceptible to sensitization to antigens known to be allergenic in humans so that sensitized animals display an immune response to the antigens that has hallmarks characteristic of allergic responses observed in humans.

40. The method of claim 39, wherein the hallmarks are selected from the group consisting of elevated antigen-specific IgE levels above about 500 ng/ml, elevated antigen-specific IgE levels above about 1000 ng/ml, elevated antigen-specific IgE levels above about 1500 ng/ml, anaphylaxis, hives, drop in body temperature, diarrhea, difficulty breathing, increased mast cell degranulation, increased histamine release, increase airway resistance, and death.

41. A method of sensitizing an animal to an antigen, the method comprising steps of:

providing an animal, wherein the animal has an inflamed gastrointestinal tract; and

administering a sensitizing composition to the animal.

42. The method of claim 41, wherein the animal is infected with a virus.

43. The method of claim 42, wherein the virus is murine mammary tumor virus (MMTV).

44. The method of claim 41, wherein the animal is infected with bacteria.

45. The method of claim 41, wherein the animal is exposed to a chemical compound that causes gastrointestinal inflammation.

46. The method of claim 45, wherein the chemical compound is an organic compound.

47. The method of claim 45, wherein the chemical compound is ethanol.